

### REMARKS/ARGUMENTS

Claims 1-3 are amended. The examiner indicated newly proposed claims 31-98 will not be examined because they were proposed after prosecution of the present application was closed and they raise new issues. Claims 1-30 remain in the application.

Applicant believes the foregoing amendments place the application in condition for allowance. Entry of the amendments and allowance of the application at an early date is respectfully requested.

Claims 1-3 are amended to recite that the multiple spiral barb disposition includes barbs spaced longitudinally along the body such that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb. Support for this amendment can be found, for example, at paragraphs [0100] to [0114], and FIGs. 5A-7 of the specification. Claims 1-3 are further amended for clarification by changing the recitation of the "random" barb disposition to --irregular--.

In the Office action, the examiner withdrew a Notice of Allowability in view of GB 1,091,282 to McKenzie.

Applicant's attorney gratefully acknowledges the interview granted by the examiner and her supervisor on August 15, 2007. Claims 1, 4 and 21-24 were discussed in view of McKenzie. Applicant discussed amendments to claim 1 to the recited twist cut multiple spiral and random barb dispositions. Applicant believes that these amendments render the present claims patentable over McKenzie. Applicant's attorney also discussed providing evidence with respect to the functionality of the barbed suture with certain claimed barb configuration parameters. Resolution on the claims was not reached. The following is consistent with the substance of the interview, with the exception of the argument directed to the rejections citing certain barb dispositions and barb configuration parameters, which Applicant contends does not state a *prima facie* case of obviousness.

More specifically, the examiner rejected claims 1-3, 10, 12, and 14 under 35 U.S.C. 102(b) as being anticipated by McKenzie. Regarding claims 1 and 10, the examiner stated that McKenzie discloses a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12), cutting the ribs (43) to produce the series of barbs (44), and twisting the suture in its longitudinal axis (pg 3, ln 128— pg 4, ln 9). Regarding claims 2 and 3, the examiner states that McKenzie further discloses the barbs may face in only one direction (Fig 6; pg 3, ln 48-51) or the suture may have a first barbed portion (35) that faces toward a first end (38) and a second barbed portion (36) that faces toward a second end (39) (Fig 9; pg 3, ln 103-109).

The Applicant respectfully submits that claims 1-3 patentably distinguish from the above reference. Claims 1-3, as amended, define a barbed suture and recite, *inter alia*, a multiple spiral disposition, an overlapping disposition, an irregular disposition, and combinations thereof, wherein the multiple spiral disposition includes barbs spaced longitudinally along the body such

that a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb. These features are neither taught nor suggested by McKenzie.

Referring to McKenzie, initially it should be noted that the following examiner's statement is incorrect:

"McKenzie discloses a barbed suture (Fig 6) wherein the barbs have a disposition on the body consisting of a twist cut multiple spiral disposition, since they are formed by twisting a monofilament (33) to produce a cruciform shape (Fig 12)..."

Referring to page 3, line 125 to page 4, line 9, and FIG. 12 of McKenzie, the McKenzie suture is made from monofilament nylon of circular cross-section. The monofilament is rolled to produce a cruciform cross section. The ribs are cut to produce barbs and the suture twisted in its longitudinal axis. This does not produce a barbed suture with a multiple spiral barb disposition as presently claimed by Applicant. The process described in the specification, wherein the suture body is twisted, cut by one or more blades, and then unwound, produces a barbed suture wherein the barbs form a single spiral along the length of the body and wherein a plane perpendicular to the longitudinal axis of the suture and cutting transversely through the suture and intersecting a barb will not intersect any other barb. This barb configuration is not disclosed or suggested by McKenzie.

Since McKenzie fails to show each and every element of the presently claimed invention, the references cannot anticipate claims 1-3. Therefore, Applicant respectfully submits that claims 1-3 are patentable over McKenzie.

The examiner rejects claims 4-9 and 21-23 under 35 U.S.C. 103(a) as being unpatentable over McKenzie. These claims recite several parameters related to barb disposition and barb configuration, including a staggered barb disposition and corresponding radial barb spacing; barb cut distance, cut angle, cut depth, and cut length; and a spirality angle between barbs. With respect to each of these claims, the examiner notes that McKenzie does not disclose the recited dimensions. However, the examiner contends that the Applicant has not disclosed that the recited parameters solve any stated problem or are for any particular purpose. The examiner goes so far to state, without basis, that "the barbed suture of McKenzie, or applicant's invention, would perform equally well with the suture having any appropriate dimension". The examiner concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have modified McKenzie such that the suture had the recited parameters because such a modification would have been considered a mere design consideration which fails to patentably distinguish over McKenzie.

Applicants respectfully submit that the rejected claims define a barbed suture with novel, non-obvious features, which provide significant, non-obvious advantages over the prior art. Importantly, as the examiner herself correctly noted, McKenzie fails to disclose any of the recited features. It is thus fair to say that McKenzie fails to recognize and thus realize the advantages which the Applicant has achieved with its invention. If any of the features were indeed obvious, it would have been disclosed in McKenzie, which is presently improperly relied

upon by the Examiner.

Moreover, the Examiner's suggestion that the claimed features are merely a matter of obvious design choice to one of ordinary skill in the art is ill-taken. Given the claimed barbed suture as described in the specification, and the fact that McKenzie does not show such a design, Applicant respectfully submits that a barbed suture as claimed is not obvious.

The dependent claims of the present application include the features discussed above and allowable for the same reasons. In addition to these distinguishing features, the barbed suture of the present invention has additional advantageous features defined in the dependent claims which further distinguish the present invention over the prior art. For example, claim 6 recites that the barbed suture is made from a suture filament having a portion that is twisted from about 2 to about 17 times per inch when the barbs are escarped into the suture filament. As explained above, McKenzie does not show twisting prior to cutting barbs. Therefore, McKenzie does not disclose or suggest this feature with its many advantages.

Regarding claims 16, 24 and 25, Applicant notes that the examiner does not appear to address the features of these claims. In particular, claim 24 is not cited at all. Accordingly, Applicant presumes the claims are allowable, particularly in view of the arguments herein.

For the foregoing reasons, the Applicant respectfully submits that claims 1-30 are now in condition for allowance. Entry of the amendments and allowance of the application at an early date is respectfully requested.

Respectfully submitted,

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